



6/17/04

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(B&W No. 003979-00002)

Applicant: Weaver, et al.  
Serial No.: 10/800,587  
Filing Date: March 15, 2004  
Examiner: Unassigned  
Group: 3763  
Conf. No.: 1652  
Title: MICROSCISSION PROCESS AND PROCEDURE

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CERTIFICATE OF EXPRESS MAIL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Express Mail Receipt No. EV436814039US  
Date of Deposit: June 16, 2004

I hereby state that the following:

- ☒ Information Disclosure Statement
- ☒ PTO-1449 Form
- ☒ Copies of Art as Cited on Page 1-2 of PTO-1449 Form
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is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, on the date indicated above and is addressed to Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Brigid Laffey

June 16, 2004  
Dated

Brigid Laffey  
Signature of person mailing above-identified papers



Docket No. 003979/00002

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT:** Weaver, et al. **EXAMINER:** Unassigned  
**SERIAL NO.:** 10/800,587 **GROUP:** 3763  
**FILED:** 15 March 2004 **CONF. NO.:** 1652  
**FOR:** Microscission Process and Procedure

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with the provisions of 37 C.F.R. §1.56 and §1.97, Applicant herewith submits the publications and/or patents shown on the attached Form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

**REMARKS**

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed within three (3) months of the Filing Date or before the mailing date of the First Office Action on the merits

It is respectfully requested that each of the documents shown on the attached form PTO-1449 be made of record in this application. Copies of these documents are in the file of related application Serial No. 09/878,155, filed 07 June 2001 and are thus not being resubmitted herein.

Information Disclosure Statement  
U.S.S.N. 10/800,587  
Page 2 of 2

Early examination and allowance of the present application are respectfully solicited.

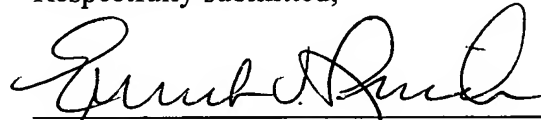
### FEE AUTHORIZATION

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Respectfully submitted,



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Date: 16 June 2004



PTO/SB/08a (05-03)



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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

3

of

8

## Complete if Known

Application Number	10/800,587
Filing Date	March 15, 2004
First Named Inventor	James C. Weaver
Art Unit	3763
Examiner Name	Not Yet Assigned
Attorney Docket Number	003979-00002

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AC2	5,630,796	20 May 97	Bellhouse, et al.	604	49	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AM	WO 00/03758	27 Jan 00	PCT			
	AN	WO 97/04832	13 Feb 97	PCT			
	AO	EO 0 417 290	20 Mar 91	EPO			
	AP						
	AQ						

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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	AS	
	AT	

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(use as many sheets as necessary)

Sheet

4

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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,019,034	05/28/1991	Weaver, et al.	604	20	
	AB	5,389,069	02/14/1995	Weaver	604	21	
	AC	6,085,115	07/04/2000	Weaver, et al.	600	509	
	AD	5,003,987	04/02/1991	Grinwald	128	734	
	AE	5,688,233	11/18/1997	Hofmann, et al.	604	20	
	AF	5,885,211	03/23/1999	Eppstein, et al.	600	309	
	AG	6,142,939	11/07/2000	Eppstein, et al.	600	309	
	AH	6,022,316	02/08/2000	Eppstein, et al.	600	309	
	AI	5,547,467	08/20/1996	Pliquett, et al.	604	203	
	AJ	5,667,491	09/16/1997	Pliquett, et al.	604	50	
	AK	5,749,847	05/12/1998	Zewert, et al.	604	49	
	AA2	5,911,223	06/15/1999	Weaver, et al.	128	898	
	AB2	5,983,131	11/09/1999	Weaver, et al.	604	20	

**FOREIGN PATENT DOCUMENTS**

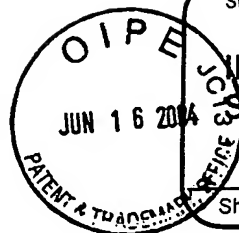
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 97/07734	03/06/1997	PCT			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	AR	Langer, R., "Drug Delivery and Targeting.," Nature, 392:S5-S10 (1998).					
	AS	Elias, P.M., et al. "Percutaneous Transport in Relation to Stratum Corneum Structure and Lipid Composition," J. Invest. Dermatol., 76(4): 297-301 (1981).					
	AT	Elias, P.M., and Menon, G.K., "Structural and Lipid Biochemical Correlates of the Epidermal Permeability Barrier," Adv. Lipid Res., 24: 1-26 (1991).					
	AU	Zewert, T.E., et al., "Creation of Transdermal Pathways for Macromolecule Transport by Skin Electroporation and a Low Toxicity, Pathway-Enlarging Molecule," Bioelectrochem. and Bioenerget., 49:11-20 (1999).					
	AV	Ilic, L., et al., "Electrochemical Creation of Microconduits in Full-Thickness Human Skin for Transdermal Drug Delivery by Pressure-Driven Flow," Proc. Internat. Symp. on Controlled Release of Bioact. Materials, Controlled Release Society, 26:178-179 (1999).					

EXAMINER

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet **5** of **8**

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Art Unit	3763
Examiner Name	Not Yet Assigned
Attorney Docket Number	003979-00002

## **U.S. PATENT DOCUMENTS**

### **OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AW	Ilic, L., et al., "Spatially Constrained Skin Electroporation with Sodium Thiosulfate and Urea Creates Transdermal Microconduits," <i>J. Control. Release</i> , 61:185-202 (1999).
AX	Yamashita, N., et al., "Scanning Electron Microscopic Evaluation of the Skin Surface after Ultrasound Exposure," <i>The Anatomical Record</i> , 247: 455-461 (1997).
AY	Tachibana, K., and Tachibana, S., "Transdermal Delivery of Insulin by Ultrasonic Vibration," <i>J. Pharm. Pharmacol.</i> , 43(4):270-271 (1991).
AZ	Mitragotri, S., et al., "Ultrasound-Mediated Transdermal Protein Delivery," <i>Science</i> , 269:850-853 (1995).
AR2	Mitragotri, S., et al., "Determination of Threshold Energy Dose for Ultrasound-Induced Transdermal Drug Transport," <i>J. Controlled Release</i> , 63:41-52 (2000).
AS2	Jacques, S.L., et al., "Controlled Removal of Human Stratum Corneum by a Pulsed Laser," <i>J. Invest. Dermatol.</i> , 88(1):88-93 (1987).
AT2	Nelson, J.S., et al., "Mid-Infrared Laser Ablation of Stratum Corneum Enhances in Vitro Percutaneous Transport of Drugs," <i>J. Invest. Dermatol.</i> , 97(5):874-879 (1991).
AU2	Eisenbraun, M.D., et al., "Examination of Parameters Affecting the Elicitation of Humoral Immune Responses by Particle Bombardment-Mediated Genetic Immunization," <i>DNA and Cell Biology</i> , 12(9):791-797 (1993).
AV2	Macklin, M.D., et al., "Immunization of Pigs with a Particle-Mediated DNA Vaccine to Influenza A Virus Protects Against Challenge with Homologous Virus," <i>J. of Virology</i> , 72(2):1491-1496 (1998).
AW2	Smith, A., et al., "Fluorescein Kinetics in Interstitial Fluid Harvested from Diabetic Skin During Fluorescein Angiography: Implications for Glucose Monitoring," <i>Diabetes Tech. &amp; Therapeut.</i> , 1(1): 21-27 (1999).
AX2	Cullander, C., "What Are the Pathways of Iontophoretic Current Flow Through Mammalian Skin?" <i>Adv. Drug Delivery Rev.</i> , 9(2/3):119-135 (1992).
AY2	Inada, H., et al., "Studies on the Effects of Applied Voltage and Duration on Human Epidermal Membrane Alteration/recovery and the Resultant Effects upon Iontophoresis," <i>Pharm. Res.</i> , 11(5):687-697 (1994).
AZ2	Green, P.G., "Iontophoretic Delivery of Peptide Drugs," <i>J. Controlled Release</i> , 41:33-48 (1996).

EXAMINER

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
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Attorney Docket Number	003979-00002

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AR3	Merino, V., et al., "Transdermal Therapy and Diagnosis by Iontophoresis," <i>TIBTech.</i> , 15:288-290 (1997).
AS3	Dinh, S.M., et al., "Upper and Lower Limits of Human Skin Electrical Resistance in Iontophoresis," <i>AICHE J.</i> , 39(12):2011-2018 (1993).
AT3	Monteiro-Riviere, N.A., et al., "Identification of the Pathway of Iontophoretic Drug Delivery: Light and Ultrastructure Studies Using Mercuric Chloride in Pigs," <i>Pharm. Res.</i> , 11(2):251-256 (1994).
AU3	Langkjaer, L., et al., "Iontophoresis of Monomeric Insulin Analogues In Vitro: Effects of Insulin Charge and Skin Pretreatment," <i>J. Control. Release</i> , 51:47-56 (1998).
AV3	Chizmadzhev, Y., et al., "Electrical Properties of Skin at Moderate Voltages: Contribution of Appendageal Macropores," <i>Biophys. J.</i> , 74: 843-856 (1998).
AW3	Prausnitz, M.R., et al., "Electroporation of Mammalian Skin: A Mechanism to Enhance Transdermal Drug Delivery," <i>Proc. Nat. Acad. Sci. USA</i> , 90:10504-10508 (1993).
AX3	Prausnitz, M.R., et al., "Methods for in Vivo Tissue Electroporation Using Surface Electrodes," <i>Drug Delivery</i> , 1(2):125-131, (1993).
AY3	Gallo, S.A, et al., "Characterization of Electric-Pulse-Induced Permeabilization of Porcine Skin Using Surface Electrodes," <i>Biophysical Journal</i> , 72: 2805-2811 (1997).
AZ3	Vanbever, R., et al., "In vivo Noninvasive Evaluation of Hairless Rat Skin after High-Voltage Pulse Exposure," <i>Skin Pharmacol. Appl. Skin Physiol.</i> , 11:23-34 (1998).
AR4	Vanbever, R., et al., "Transdermal Delivery of Fentanyl: Rapid Onset of Analgesia Using Skin Electroporation," <i>J. Controlled Release</i> , 50: 225-235 (1998).
AS4	Chen, T., et al., "Skin Electroporation Causes Molecular Transport Across the Stratum Corneum Through Localized Transport Regions," <i>J. Invest. Dermatol. Symposium Proceedings</i> , 3:159-165 (1998).
AT4	Chen, T., et al., "Skin Electroporation: Rapid Measurements of the Transdermal Voltage and Flux of Four Fluorescent Molecules Show a Transition to Large Fluxes near 50 V," <i>J. of Pharm. Sci.</i> , 87(11):1368-1374 (1998).
AU4	VanBever, R., et al., "Comparison of the Effects of Short, High-voltage and Long, Medium-Voltage Pulses on Skin Electrical and Transport Properties," <i>J. Controlled Release</i> , 69:35-47, (1999).
AV4	Zewert, T.E., et al., "Transdermal Transport of DNA Antisense Oligonucleotides by Electroporation. <i>Biochem. Biophys. Res. Comm.</i> , 212(2): 286-292 (1995).

EXAMINER

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Substitute for form 1449A/PTO

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Sheet 7 of 8**Complete if Known**

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- |     |  |
|-----|--|
| AW4 | Prausnitz, M.R., et al., "Transdermal Delivery of Heparin by Skin Electroporation," <i>Biotechnology</i> , 13: 1205-1209 (1995).   |
| AX4 | Heise, H.M., "Non-Invasive Monitoring of Metabolites Using Near Infrared Spectroscopy: State of the Art," <i>Horm. Metab. Res.</i> , 28:527-534 (1996).  |
| AY4 | Fischer, U., et al., "Assessment of Subcutaneous Glucose Concentration: Validation of the Wick Technique as a Reference for Implanted Electrochemical Sensors in Normal and Diabetic Dogs," <i>Diabetologia</i> , 30(12):940-945 (1987).                                       |
| AZ4 | Quan, K.M., et al., "Glucose Determination By a Pulsed Photoacoustic Technique: An Experimental Study Using A Gelatin-Based Tissue Phantom," <i>Phys. Med. Biol.</i> , 38(12):1911-1922, (1993).   |
| AR5 | Tamada, J.A., et al., "Measurement of Glucose in Diabetic Subjects Using Noninvasive Transdermal Extraction," <i>Nature Medicine</i> , 1(11):1198-1202 (1995).   |
| AS5 | Ito, N., et al., "Transcutaneous Blood Glucose Monitoring System Based on ISFET Glucose Sensor and Studies on Diabetic Patients," <i>Frontiers Med. Biol. Engng.</i> , 6(4):269-280 (1995).  |
| AT5 | Berger, A.J., "Feasibility of Measuring Blood Glucose Concentration by Near-infrared Raman Spectroscopy," <i>Spectrochim. Acta</i> , 53(Part A):287-292 (1997).  |
| AU5 | Schiffman, et al., "Airway Humidification in Mechanically Ventilated Neonates and Infants: A Comparative Study of a Heat and Moisture Exchanger vs. a Heated Humidifier Using a New Fast-response Capacitive Humidity Sensor," <i>Crit. Care Med.</i> 25(10):1755-1760 (1997). |
| AV5 | Ohhashi, et al., "Human Perspiration Measurement," <i>Physiol. Meas.</i> 19(4): 449-461 (1998).  |
| AW5 | Pliquett, U.F., et al. "Imaging of Fluorescent Molecules and Small Ion Transport Through Human Stratum Corneum During High-Voltage Pulsing: Localized Transport Regions Are Involved," <i>J. Biophys. Chem.</i> , 58:185-204, (1996).  |
| AX5 | Prausnitz, M.R., et al., "Imaging Regions of Transport Across Human Stratum Corneum During High Voltage and Low Voltage Exposures," <i>J. Pharm. Sci.</i> , 85(12):1363-1370, (1996).  |
| AY5 | Weaver, J.C., et al. "Theory of Electrical Creation of Aqueous Pathways Across Skin Transport Barriers," <i>Advanced Drug Delivery Reviews</i> , 35(1):21-39, (1999).  |
| AZ5 | Gowrishankar, T.R., et. al., "Spatially Constrained Localized Transport Regions Due to Skin Electroporation," <i>J. controlled Release</i> , 60(1): 101-110 (1999).  |

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8 of 8

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|-----|--|
| AR6 | Hikima, T., et al., "Effect of Ultrasound Application on Skin Metabolism of Prednisolone 21-Acetate," <i>Pharm. Res.</i> , 15(11):1680-1683 (1998).  |
| AS6 | Wu, J., et al., "Defects Generated in Human Stratum Corneum Specimens by Ultrasound," <i>Ultrasound in Med. &amp; Biol.</i> 24(5):705-710 (1998).  |
| AT6 | Henry, S., et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery," <i>J. Pharm. Sci.</i> 87(8):922-925 (1998).  |
| AU6 | Miyajima, et al., "Effect of Polymer/Basic Drug Interaction on the Two-Stage Diffusion-Controlled Release from a Poly(L-lactic Acid) Matrix," <i>J. Controlled Rel.</i> 61(3):295-304 (1999).                  |
| AV6 | Simon, L.D., et al., "Mechanisms Controlling Diffusion and Release of Model Proteins Through and From Partially Esterified Hyaluronic Acid Membranes," <i>J. Controlled Rel.</i> 61(3):267-279 (1999).         |
| AW6 | Prestwich, G.D., et al., "Controlled Chemical Modification of Hyaluronic Acid: Synthesis, Applications, and Biodegradation of Hydrazide Derivatives," <i>J. Control. Release</i> 53:93-103 (1998).             |
| AX6 | Koo, T-W., et al., "Reagentless Blood Analysis by Near-Infrared Raman Spectroscopy," <i>Diabetes Tech. Therapeut.</i> , 1(2):153-157 (1999).   |
| AY6 | Berger, A.J., et al., "Multicomponent Blood Analysis by Near-Infrared Raman Spectroscopy," <i>Appl. Optics</i> 38(13):2916-2926 (1999).  |
| AZ6 | Longridge, D.J., et al., Effects of Payload Per Unit Area on Dermal Powderject® Delivery of Testosterone to Conscious Rabbits," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 25:595-596 (1998). |
| AR7 | Uchida, M., et al., "Transdermal Microparticle Delivery by a Supersonic Helios™ Gun System," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 25:575-576 (1998).                                    |
| AS7 | Sage, B.H., Jr., "Iontophoresis" CRC Press, Inc., Chapter 15.1 Percutaneous Penetration Enhancers 351-368 (1995).  |
| AT7 | Weaver, J.C., and Langer, R., "Electrochemical Creation of Large Aqueous Pathways: an Approach to Transdermal Drug Delivery," <i>Progress in Dermatology</i> , 33:1-10 (1999). November 26, 2001               |
| AU7 | McAllister, D.V., et al., "Microfabricated Microneedles: A Novel Approach to Transdermal Drug Delivery," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 25:30-31 (1998).                          |
| AV7 | Scott, E.R., et al., "Direct Imaging of Ionic Pathways in Stratum Corneum Using Scanning Electrochemical Microscopy," <i>Solid State Ionics</i> , 53-56 (Part 1):176-183 (1992).                               |
| AW7 | Weaver, J.C. and Langer, R. "Electrochemical Creation of Large Aqueous Pathways: an Approach to Transdermal Drug Delivery," <i>Progress in Dermatology</i> , 33: 1-10 (1999) November 26, 2001                 |

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